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Anthony Nicolas Kalloo

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NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

SHAY, DAVID M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* ANTHONY NICOLAS KALLOO and  
SERGEY VENIAMINOVICH KANTSEVOY

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Appeal 2009-006379  
Application 09/815,336  
Technology Center 3700

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Decided: March 18, 2010

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Before LINDA E. HORNER, KEN B. BARRETT, and  
FRED A. SILVERBERG, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*

DECISION ON APPEAL

## STATEMENT OF THE CASE

Anthony Nicolas Kalloo and Sergey Veniaminovich Kantsevoy (Appellants) seek our review under 35 U.S.C. § 134 (2006) of the Examiner's decision rejecting claims 1, 2, 4-19, 21, 22, and 36. We have jurisdiction under 35 U.S.C. § 6(b) (2006).

## SUMMARY OF DECISION

We REVERSE.

## THE INVENTION

Appellants' claimed invention is a procedure for accessing and examining and/or conducting surgical procedures in a body cavity. Spec. 1:6-7. Claim 1, reproduced below, is representative of the subject matter on appeal.

1. A method for accessing an interior of a cavity of a mammal, said method comprising:

positioning an elongated flexible conduit to extend from an exterior of the mammal through a natural orifice into and along at least a portion of the digestive tract to a target wall segment in the digestive tract;

forming an incision in said target wall segment;

advancing a distal end of said flexible conduit so that the distal end of said conduit extends through said wall;

after forming said incision and advancing the distal end of said flexible conduit through said wall, anchoring said distal end with respect to said wall;

advancing an endoscope through said conduit so that a distal end of said endoscope is disposed adjacent or distal to said distal end of said conduit;

viewing at least one of a tissue and an organ within said cavity;

releasing said anchor;

withdrawing said conduit and said endoscope through said wall; and

closing said incision,

further comprising, after said forming an incision and before said advancing said conduit, dilating said incision to facilitate passage of said conduit therethrough, wherein said dilating comprises dilating with an inflatable balloon.

#### THE EVIDENCE

The Examiner relies upon the following evidence:

Wilk	US 5,297,536	Mar. 29, 1994
McNeely	US 5,458,583	Oct. 17, 1995
Laufer	US 6,030,365	Feb. 29, 2000

#### THE REJECTIONS

Appellants seek review of the following rejections:

1. The Examiner rejected claims 1, 2, 4, 5, 7-13, 15-19, 21, 22, and 36 under 35 U.S.C. § 103(a) as being unpatentable over Wilk and McNeely.
2. The Examiner rejected claims 6 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Wilk, McNeely, and Laufer.

#### ISSUE

The Examiner found Wilk teaches the method of claim 1, relying on Wilk's endoscope sheath to meet the claimed flexible conduit, except that Wilk does not specifically mention dilating the opening after it is made or the use of balloons. Ans. 3-5. The Examiner found that McNeely teaches a

method of dilating a stomach wall using a balloon. Ans. 3. The Examiner determined that it would have been obvious to employ the dilation steps of McNeely in the method of Wilk. Ans. 3.

Appellants argue that “[e]ven if the sheath is provided as a part of the endoscope in Wilk and that sheath is advanced through the incision, such a sheath does not read on the claimed flexible conduit which is not only advanced through the incised target wall segment but is then anchored to the wall segment and an endoscope is thereafter passed through it.” Reply Br. 2.

The issue presented by this appeal is:

Would the combination of Wilk and McNeely, as proposed by the Examiner, have resulted in the claimed method including the steps of anchoring a distal end of a flexible conduit with respect to a wall in the digestive tract and advancing an endoscope through the flexible conduit?

#### FINDINGS OF FACT

We find that the following enumerated findings are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

1. Wilk discloses an endoscopic assembly 20 comprising an outer tube 22 and an endoscopic insertion member 32. Wilk, col. 4, ll. 34-36 and 43-44; fig. 4.
2. Wilk discloses that tube 22 and endoscopic insertion member 32 may be inserted together through a natural body opening into an organ, and that upon selection of a suitable entry site, endoscopic

insertion member 32 is withdrawn at least partially from 22 to facilitate formation of a negative-pressure connection between the distal end of tube 22 and the wall of the organ. Wilk, col. 4, ll. 59-68.

3. Wilk discloses that prior to incising the wall of a natural body cavity or organ, a distal end of the tube 22 is brought into engagement with the wall, and suction is applied to connect the tube 22 to the wall. Wilk, col. 4, ll. 54-58; fig. 5A.
4. Wilk discloses that once the tube 22 is connected to the wall, a needle is inserted through a biopsy channel 52 in the endoscopic insertion member 32 to pierce the wall of the cavity, the abdominal cavity is insufflated, the needle is removed, an endoscopic incising instrument is passed through the biopsy channel 52 to perforate the wall of the cavity, a distal end of the endoscope 32 is moved through the tube 22 and through the perforation, the endoscope is used to visually inspect internal body tissues, and then a surgical operation is executed on the internal body tissues by manipulating an endoscope surgical instrument passed along the endoscope and through the perforation into the abdominal cavity. Wilk, col. 2, ll. 43-52 and col. 5, ll. 1-18.
5. Wilk discloses in one embodiment, endoscopic insertion member 32 is provided with a sheath having an expandable channel, and the incising instrument is inserted through this channel upon insertion of the endoscope through the natural body opening and into the

natural body cavity, and the surgical instrument is inserted through the sheath channel prior to executing a surgical operation. Wilk, col. 2, ll. 15-22, col. 3, ll. 52-61.

6. Wilk does not disclose anchoring the distal end of its sheath with respect to the wall of the digestive tract.
7. McNeely discloses a method of placing a gastrostomy catheter into the interior of a patient's stomach through the secured walls of the patient's stomach and abdomen. McNeely, col. 1, ll. 64-67.
8. McNeely discloses using a balloon on a dilatation catheter to dilate a passageway formed through the abdominal and stomach walls, then deflating the balloon and advancing the gastrostomy catheter over the dilatation catheter. McNeely, col. 3, ll. 2-8 and ll. 22-28.
9. In McNeely, once the distal end of the gastrostomy catheter is disposed well within the interior of the stomach, the dilatation catheter is removed, and the distal end of the gastrostomy catheter is secured within the stomach by inflating a balloon on the distal end of the gastrostomy catheter, withdrawing the catheter until the inflated balloon is urged snugly against the interior of the stomach wall, and then advancing distally a sealing ring on the shaft of the gastrostomy catheter until it is pressed against the exterior of the abdominal wall. McNeely, col. 3, ll. 29-40.

#### ANALYSIS

We cannot find in the Examiner's Answer any specific discussion or findings as to how the combination of Wilk and McNeely would have

resulted in the sheath of Wilk being anchored to the wall segment, or any discussion or findings as to how the combination of Wilk and McNeely would have resulted in the endoscope of Wilk being passed through the sheath. While the Examiner explains why one would have substituted the sealing method of McNeely for the sealing method of Wilk, the Examiner is referring in this explanation to Wilk's use of suction to seal the tube 22 to the wall segment. Ans. 5-7. Even if one were to make the substitution suggested by the Examiner, this modification would not result in Wilk's endoscope sheath (i.e., the flexible conduit) being anchored to the wall segment as called for in claim 1, since Wilk discloses that the endoscope and sheath pass through the tube 22 (Facts 4, 5).

Further, we find no disclosure in Wilk of anchoring the sheath to the wall segment (Facts 1-6). While McNeely discloses securing its gastrostomy catheter within the stomach, McNeely's catheter is a permanent or semi-permanent feeding tube which has to be anchored to the stomach wall to prevent the tube from being pulled out inadvertently (Facts 7-12). The Examiner has not articulated any persuasive reasoning why one having ordinary skill in the art would have been led to anchor Wilk's sheath to the wall segment in view of McNeely's teaching to secure a feeding tube to the stomach wall. Also, Wilk appears to disclose that the sheath is part of the endoscope such that the two are advanced simultaneously (Fact 5). Thus, Wilk does not appear to disclose the step of advancing an endoscope *through* the flexible conduit as claimed. As such, the Examiner has not made sufficient findings and has not provided adequate reasoning to explain



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why one having ordinary skill in the art would have arrived at the method of claim 1 in view of Wilk and McNeely. The rejection of claims 2, 4, 5, 7-13, 15-19, 21, 22, and 36 based on Wilk and McNeely likewise fails by virtue of their dependence from claim 1.

Claims 6 and 14 also depend from claim 1. The rejection of claims 6 and 14 based on Wilk, McNeely, and Laufer likewise fails because the Examiner relies on Laufer to teach the use of a cauterizing incision instrument and the use of balloons to seal the conduit in the organ wall and does not rely on Laufer to cure the deficiencies noted above in the combination of Wilk and McNeely. Ans. 4.

#### CONCLUSION

The combination of Wilk and McNeely, as proposed by the Examiner, would not have resulted in the claimed method including the steps of anchoring a distal end of a flexible conduit with respect to a wall in the digestive tract and advancing an endoscope through the flexible conduit.

#### DECISION

The decision of the Examiner to reject claims 1, 2, 4-19, 21, 22, and 36 is reversed.

#### REVERSED

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NIXON & VANDERHYE PC  
901 NORTH GLEBE ROAD  
11TH FLOOR  
ARLINGTON VA 22203